

SECTION 3
quantex C3 - 510(k) SUMMARY
(Summary of Safety and Effectiveness)

Submitted by:

Betty Lane
Director, Regulatory Affairs
Instrumentation Laboratory Company
113 Hartwell Avenue
Lexington, MA 02173
phone (617) 861-4182
fax (617) 861-4464

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Contact Person:

Betty Lane
phone (617) 861-4182

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Name of the device:

quantex C3:	8 x 6 mL anti-human C3	P/N 3000-22136
	2 x 100 mL Buffer	P/N 3000-22130

Classification name(s):

866.5240 Complement components immunological test systems Class II

Identification of predicate device(s):

IL Test™ C3 #K920007/B

Description of the device/intended use(s):

This product permits the quantitative *in vitro* diagnostic determination of Complement 3 in serum and plasma on the ILab Clinical Chemistry System by turbidimetric immunoassay method. C3 is one of a group of serum proteins which destroy infectious agents. Measurement of this protein aids in the diagnosis of immunologic disorders, especially those associated with deficiencies of C3.

Statement of how the Technological Characteristics of the Device compare to the Predicate device:

Biokit's quantex C3 is substantially equivalent in performance, intended use, safety and effectiveness to the predicate, IL Test™ C3 -- 510(k) #K920007/B.

Summary of Performance Data:

A comparative performance study was performed with IL Test™ C3 on a Monarch Clinical Chemistry System and Biokit's quantex C3 on an ILab Clinical Chemistry System. Method comparison studies evaluated C3 levels of fifty serum samples on the respective instruments. The correlation (*r*) in these studies was 0.9842.